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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,578	01/30/2004	Robert G. Lowery	112520.00004	8954

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EXAMINER	
STAPLES, MARK	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/769,578	LOWERY ET AL.	
	Examiner	Art Unit	
	Mark Staples	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-15 and 19-24, drawn to methods and assays of detecting a donor-product of a group transfer reaction, classified in class 435, subclass 6.

   II. Claims 16-18, drawn to antibodies produced against a donor product of a group transfer reaction, classified in class 424, subclass 130.1+.

   III. Claims 25-27, drawn to kits for characterizing a donor-product from a group transfer reaction comprising a macromolecule and a tracer classified in class 424, subclass 94.1.

2. The inventions are independent or distinct, each from the other because:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the antibody in Group II can be used in a materially different process than Group II; the antibody can be used on an affinity column to purify antigen. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in

view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the tracer in Group II can be used in a materially different process than Group II; the tracer can be used to determine the source of a stream emerging from a cave or the source of a spring. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

The antibodies of Group II and the kits with macromolecules and tracer of Group III are related. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can

have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the antibody claims do not overlap the scope of the kit claims and vice versa, as evidenced by the different structures and function of an antibody which binds antigens and a kit for characterizing a donor-product. An antibody is protein with structure for binding specific antigens whereas the kit has structures of both a macromolecule which can have the different protein structure of an inactivated enzyme and a tracer with the relatively smaller non-protein structure of a fluorophore. Additionally, the Group I and Group II are not obvious variants of each other based on based on the distinct structures and functions noted above. Lastly the antibodies and kits have materially different functions *as* noted above. Thus by virtue of the different functions of Groups II and III, these related inventions are distinct.

Election of Species

3. This application contains claims directed to the following patentably distinct species in Group I and III as follows.

Group I

Species of acceptor

a. Polypeptide (claim 3 in part)

b. Protein (claim 3 in part)

c. Nucleic acid (claim 3 in part)

d. Lipid (claim 3 in part)

e. Carbohydrate (claim 3 in part)

f. Small molecule substrate (claim 3 in part)

Species of donor-product

a. Nucleotide

b. Non nucleotide

i. s-adenosylhomocysteine (claims 3 and 22 in part)

ii. nicotinamide (claims 3 and 22 in part)

iii. coenzyme A (claims 3 and 22 in part)

Species of accepter-x, covalent adduct

a. Phosphate (claim 3 in part)

b. Sulfate (claim 3 in part)

c. Carbohydrate (claim 3 in part)

d. Naturally occurring amino acid (claim 3 in part)

e. Synthetically derived amino acid (claim 3 in part)

f. ADP-ribose (claim 3 in part)

g. Nucleotide (claim 3 in part)

h. Methyl moiety (claim 3 in part)

i. Acetyl moiety (claim 3 in part)

j. Glutathione moiety (claim 3 in part)

Species of Macromolecule

a. Antibody (claim 4 in part)

i. Monoclonal (claim 5 in part)

ii. Polyclonal (claim 5 in part)

iii. Recombinant (claim 5 in part)

b. Polypeptide (claim 4 in part)

c. Protein (claim 4 in part)

d. Nucleic acid molecule (claim 4 in part)

e. Inactivated enzyme (claim 4 in part)

Species of Tracer

a. fluorescent molecule (claim 7 in part)

i. Conjugated to a nucleotide (claim 7 in part)

ii. Conjugated to a non-nucleotide (claim 7 in part)

b. chemiluminescent molecule (claim 7 in part)

i. Conjugated to a nucleotide (claim 7 in part)

ii. Conjugated to a nucleotide (claim 7 in part)

Species of Catalytic activity

a. chemical activity (claim 9 in part)

b. enzymatic activity(claim 9 and 19 in part)

i. sulfotransferase (claims 9 and 21 in part)

ii. kinase (claims 9 and 21 in part)

iii. UDP-glucuronosyltransferase (claims 9 and 21 in part)

iv. Methyl transferase (claims 9 and 21 in part)

v. Acetyl transferase (claims 9 and 21 in part)

vi. Glutathione transferase (claims 9 and 21 in part)

vii. ADP ribosyltransferase (claims 9 and 21 in part)

c. a specified combination of enzymatic activity below and chemical activity (claim 9 in part)

i. sulfotransferase (claim 9 in part)

ii. kinase (claim 9 in part)

iii. UDP-glucuronosyltransferase (claim 9 in part)

iv. Methyl transferase (claim 9 in part)

v. Acetyl transferase (claim 9 in part)

vi. Glutathione (claim 9 in part)

vii. ADP ribosyltransferase (claim 9 in part)

Species of Immunoassay

a. FPIA (claim 11 in part)

b. FRET (claim 11 in part)

c. ELISA (claim 11 in part)

d. Chemiluminescence immunoassay (claim 11 in part)

Species of Fluorophore

a. fluorescein (claim 23 in part)

b. rhodamine (claim 23 in part)

c. Texas red (claim 23 in part)

d. a derivative of above (claim 23 in part)

Group III

Species of Macromolecule

a. antibody (claim 25 in part)

b. inactivated enzyme (claim 25 in part)

Species of Fluorophore

a. fluorescein (claim 27 in part)

b. rhodamine (claim 27 in part)

c. Texas red (claim 27 in part)

d. a derivative of above (claim 27 in part)

The species are independent or distinct because each species is a patentably distinct molecule with exception of the species of immunoassay. Each immunoassay is a patentably distinct method.

This application contains claims directed to the following patentably distinct species for Group I: acceptors, donor products, acceptor-x's, macromolecules, tracers, catalytic activities, immunoassays, and fluorophores; and for Group III: macromolecules and fluorophores.

The species are independent or distinct because each acceptor is a structurally different and patentably distinct molecule, each donor products is a structurally different and patentably distinct molecule, each acceptor-x's is a structurally different and patentably distinct molecule, each macromolecule is a structurally different and patentably distinct molecule, each tracer is a structurally different and patentably distinct molecule, each catalytic activity is a structurally different and patentably distinct molecule, each immunoassay is a method with different steps and patentably distinct process, each fluorophore is a structurally different and patentably distinct molecule,

each macromolecule is a structurally different and patentably distinct molecule, and each fluorophore is a structurally different and patentably distinct molecule.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 16, and 19 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

For Group I, that means applicant must elect a single specified species of acceptor, a single specified species of donor product, a single specified species of acceptor-x, a single specified species of macromolecule, a single specified species of tracer, a single specified species of catalytic activity, a single species of immunoassay, and a single specified species of fluorophore. For Group III, that means applicant must elect a single specified species of macromolecule and a single species of fluorophore, with specification of a single derivative if elected. Specified means that a single molecule must be identified. For example, election of purified human albumin would be a single specified protein of acceptor.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Because these species are independent or distinct for the reasons given above and the species require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Notice of Possible Rejoinder

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain

dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Close

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples
Examiner
Art Unit 1637
July 19, 2006

MS

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

7/19/06